Complete Summary

GUIDELINE TITLE

Guidelines for office endoscopic services.

BIBLIOGRAPHIC SOURCE(S)

Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Guidelines for office endoscopic services. Los Angeles (CA): Society of American Gastrointestinal Endoscopic Surgeons (SAGES); 2004 Mar. 6 p. [7 references]

GUIDELINE STATUS

This is the current release of the guideline.

This guideline updates a previous version: Society of American Gastrointestinal Endoscopic Surgeons (SAGES). Guidelines for office endoscopic services. Surg Endosc 1998 Feb;12(2):191-2.

COMPLETE SUMMARY CONTENT

SCOPE

METHODOLOGY - including Rating Scheme and Cost Analysis RECOMMENDATIONS EVIDENCE SUPPORTING THE RECOMMENDATIONS BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS QUALIFYING STATEMENTS IMPLEMENTATION OF THE GUIDELINE INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Gastrointestinal disorders

GUIDELINE CATEGORY

Diagnosis Screening

DISCLAIMER

CLINICAL SPECIALTY

Anesthesiology Gastroenterology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To maintain high standards of practice for gastrointestinal endoscopy in the office setting

TARGET POPULATION

Patients with gastrointestinal symptoms and patients being screened for gastrointestinal cancer

INTERVENTIONS AND PRACTICES CONSIDERED

Office endoscopic services:

- Endoscopic privileges
- Prudent patient selection for procedure
- Proper patient instruction prior to procedure
- Safe conduction of conscious sedation
- Availability of emergency transport as needed
- Availability of equipment required to perform endoscopy
- Sufficient recovery of patients from procedure and sedation
- Preventive maintenance and testing of endoscopy equipment
- Implementation of protocols for personnel and patient protection from infectious disease
- Maintenance of patient records
- Documentation of informed consent for the procedure

MAJOR OUTCOMES CONSIDERED

Not stated

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Not stated

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

This statement was reviewed and approved by the Board of Governors of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) March 2004.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Introduction

Many gastrointestinal endoscopy procedures can be performed safely in the office setting. High standards of practice, similar to those in the institutional setting, should be maintained for office gastrointestinal endoscopy.

Endoscopic Privileges

The office setting should not provide an opportunity for practice of inadequately trained and experienced endoscopists. Office endoscopists must meet accepted standards of training and experience and should qualify for and hold comparable privileges in an institutional setting.

Physical Facilities

Facilities should have been constructed in accordance with local and regional building codes, and those recommended by applicable credentialing organizations, and should be certified as an Ambulatory Surgery Center, or be capable of certification. Patient changing areas should be made available away from common areas and a secure location for storing belongings and appropriate bathroom facilities must also be available. The facility should comply with the standards of the Americans with Disabilities Act. A waiting room should be available for family members, and appropriate consultation and treatment rooms must be constructed to assure patient privacy. Mechanisms for the safe evacuation of conscious and sedated patients must exist.

Endoscopy suites should be a minimum of 200 square feet in size, and should provide the following as a minimum: 1) Reduced illumination from ambient light, 2) Sized for passage of a rolling stretcher through all doorways and passages, 3) Unrestricted access to both sides, and head and foot of the patient, 4) Unimpeded view of monitoring equipment, 5) Sufficient storage for supplies, 6) Appropriate ventilation, 7) Sound and sight privacy boundaries, and 8) Mechanisms for summoning emergency personnel that can be activated without leaving the patient.

Patient and Procedure Selection

Prudent selection of both procedures and patients appropriate for office endoscopy is critical. Procedures having intrinsic risk or requiring technology not available in the surgeon's office may be most appropriately performed in an institutional setting.

All patients scheduled for endoscopic procedures should be assigned an anesthesia risk score, using the American Society of Anesthesiologists (ASA) score. Patients with an ASA score of IV should not undergo endoscopy in the office setting. Patients with an ASA score of III should be further assessed for appropriateness of the office setting.

Patient Safety

Patients should receive clear pre procedure instructions. Confirmation of important compliance issues such as NPO status should be documented. Any modifications to standing medication schedules should be provided at the time of scheduling.

Conscious sedation used as an adjunct to endoscopic procedures must be administered safely. Intravenous access should be established prior to administering sedatives, and maintained until the patient has recovered sufficiently to permit safe discharge. There must be appropriate monitoring and expertise in managing potential associated complications such as respiratory depression and cardiac arrest. Baseline pulse, respiratory rate, oxygen saturation, and blood pressure should be recorded before administration of any sedatives. Pulse oximetry, cardiac monitoring, automated blood pressure recording, and supplemental oxygen should be routinely employed. Emergency medications and equipment used for cardiopulmonary resuscitation, including adequate oral suction, a defibrillator, ambu bag, laryngoscope, and emergency airway tray must be readily available and checked on a daily basis. Staff members should be appropriately trained in resuscitative efforts, and provide documentation of certification in courses such as Basic Cardiac Life Support (BCLS) and Advanced Cardiac Life Support (ACLS); an ACLS certified provider must accompany all sedated patients throughout their stay. An assistant trained at least in BCLS should be present during all procedures to monitor the patient. During particularly complex or instrument-intensive procedures, where the assistant is likely to be too busy assisting the physician to adequately monitor the patient, a second assistant must be made available to monitor and care for the patient. A registered nurse should be available in the recovery area. A formal transport agreement with an acute care facility capable of managing endoscopic complications must be in place and easily executed when necessary.

Medications must be stored in a secure location, and appropriate compliance with the Controlled Substances Act must be documented. Sedatives should be stored in double-locked cabinets, and a log of medication expiration dates should be maintained. Appropriate reversal agents and experience with their use should be available.

Patient care should not be compromised by a lack of equipment required to perform the proposed procedure in the office setting.

All office endoscopy patients must be sufficiently recovered from procedures and sedation prior to discharge, and should meet uniform standard discharge criteria. Patients who receive sedation must have their vital signs, respiratory status, and mentation monitored in a manner consistent with that utilized for patients treated in the hospital setting. If sedation has been used, the patient must be accompanied by a responsible adult at discharge, and be transported home and prohibited from driving or engaging in even low risk activities for a standardized period of time dictated by the sedative agents utilized. Written instructions regarding common complications, directions for returning for emergency evaluation and caution as to continued functional impairment for many hours following conscious sedation are appropriate and should be provided to all patients.

A qualified professional should do periodic preventive maintenance and testing of equipment, and a service log should be maintained for all equipment. Guard rails, wide procedure tables and other appropriate means should be used as necessary to prevent falls and mechanical injury during and after endoscopic examinations.

Standard protocols for both personnel and patient protection from infectious disease must be rigorously observed including body fluid isolation, proper specimen handling as well as proper instrument cleansing and disinfection. Separate sinks should be available for hand washing and for secretion disposal. Endoscopes should be cleaned to a high level of disinfection, as outlined in the Standards for Infection Control and Reprocessing of Flexible Gastrointestinal Endoscopes as issued by the Society of Gastroenterology Nurses and Associates. Reprocessing should be done in a well ventilated room separate from patient care areas, and physical separation of clean and contaminated equipment is vital to avoid cross-contamination. Occupational Safety & Health Administration (OSHA) Bloodborne Pathogens regulations must be adhered to as required locally, regionally, and nationally.

Records and Quality Assurance

Each patient should have at minimum a current brief history and physical examination, reviewed by the endoscopist immediately prior to the procedure. Serious cardiopulmonary or other disease should be excluded by appropriate clinical and, if necessary, laboratory evaluation.

The patient chart should contain the clinical examination and evaluation, a list of medication allergies and current medications, the justification for the procedure, the description of the endoscopy and pathology found, and the patient's status on discharge. Informed consent for the procedure should be documented in the chart consistent with local professional standards and applicable state law.

Records should be maintained so that complications and problems can be identified and compliance with recommendations for clinical and endoscopic care ensured. Records and clinical documents should adhere to the same standards required for institutions by the Joint Commission on Accreditation of Healthcare Organizations and other regulatory agencies, and should conform to Health Insurance Portability and Accountability Act standards and those others in effect.

There should be an appropriate mechanism of relating findings and the results of pathologic studies to patients and referring physicians, as well as for the tracking of specimens. Indications, findings, treatment results, and complications should be kept in a database, and periodic peer review of this data should be performed. Written policy and procedure manuals should be maintained and kept up to date, and a written agreement with a Clinical Laboratory Improvement Act (CLIA)-certified pathology lab should be maintained for the processing of specimens.

Appropriate records should be kept of accepted indicators that reflect quality levels such as: 1) Cancellation of booked procedures, 2) Unplanned admission to the operating room, 3) Unplanned overnight admission, and 4) Delay in patient discharge.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is not specifically stated for each recommendation.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate standards of practice for gastrointestinal endoscopy performed in the office setting

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

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Guidelines are applicable to all physicians who address the clinical problems without regard to the specialty training or interests and are intended to indicate the preferable but not necessarily the only acceptable approaches. Guidelines are intended to be flexible. Given the wide range of specifics in any health care problem, the surgeon must always choose the course best suited to the individual patient and the variables in existence at the moment of decision.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness Staying Healthy

IOM DOMAIN

Safety

IDENTIFYING INFORMATION AND AVAILABILITY

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1996 (revised 2004 Mar)

GUIDELINE DEVELOPER(S)

Society of American Gastrointestinal and Endoscopic Surgeons - Medical Specialty Society

SOURCE(S) OF FUNDING

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES)

GUIDELINE COMMITTEE

Committee on Standards of Practice

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available from the <u>Society of American Gastrointestinal and</u> Endoscopic Surgeons (SAGES) Web site.

Print copies: Available from the Society of American Gastrointestinal Endoscopic Surgeons (SAGES), 11300 W. Olympic Blvd., Suite 600, Los Angeles, CA 90064;

Web site: www.sages.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on November 19, 1999. The information was verified by the guideline developer on February 15, 2000. This NGC summary was updated by ECRI Institute on May 3, 2007. The updated information was verified by the guideline developer on May 13, 2007.

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